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30827 7590 06/27/2011 MCKENNA LONG & ALDRIDGE LLP 1900 K STREET, NW			EXAMINER	
			GERIDO, DWAN A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
Office Ashieu Ocument	10/576,345	MARCHAND ET AL.		
Office Action Summary	Examiner	Art Unit		
	Dwan A. Gerido	1777		
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
1) ☐ Responsive to communication(s) filed on 11 A 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This 3) ☐ Since this application is in condition for alloware closed in accordance with the practice under E	s action is non-final.  nce except for formal matters, pro			
Disposition of Claims				
4) ☑ Claim(s) 1-27 and 29-46 is/are pending in the 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 1-27, 29-46 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.			
Application Papers				
9) The specification is objected to by the Examine 10) The drawing(s) filed on 18 April 2006 is/are: a)  Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	☑ accepted or b)☐ objected to drawing(s) be held in abeyance. See tion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary			
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:			

Art Unit: 1777

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 4. Claims 1, 4, 10, 11, 12, 15, 17, 19, 20, 29-35, 38, 42, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Wohlstadter et al., (US 2001/0021534).

5. Regarding claims 1, 15, 40, and 42, Brennan teaches a substrate and a method of forming a substrate comprising an active surface that is non-wetting with respect to a sample liquid (column 4 lines 38-43), a hydrophobic region (capture zone) and a hydrophilic region (operating zone) wherein chemical operations are carried out between the hydrophilic region (operating zone) and the liquid of interest (column 5 lines 5-23, column 7 lines 14-26), and a means for supplying the sample liquid (column 5 lines 56-61). Brennan also teaches the device being utilized to determine a nucleic acid sequence thereby reading on the claimed nucleic acid chip of claim 40. Brennan does not explicitly teach a capture zone that is wetting with respect to the liquid of interest.

Page 3

Wohlstadter et al., teach a multi-array surface for diagnostic testing wherein hydrophobic binding domains are surrounded by hydrophilic regions, or hydrophilic binding domains are surrounded by hydrophobic regions (paragraph 0159). Wohlstadter et al., teach that it is advantageous to utilize hydrophilic or hydrophobic regions as a means of controlling the spread or wetting of a fluid or gel applied to the binding domains (paragraph 0159). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Wohlstadter et al., to form a hydrophilic region surrounding a hydrophobic binding domain in order to control the spread of wetting of a fluid or gel as taught by Wohlstadter et al.

- 6. Regarding claim 4, Brennan teaches the device wherein the capture zone (individual wells) exhibits chemical capture of the sample liquid (column 7 lines 45-53).
- 7. Regarding claim 10, Brennan teaches a surface rendered wetting by grafting a chemical substance onto the surface (column 5 lines 19-23).

- 8. Regarding claim 11, Brennan teaches glass as the surface (column 5 lines 19-23).
- 9. Regarding claim 12, Brennan teaches the grafting material as silane placed on the surface by silanization (column 5 lines 19-23).
- 10. Regarding claim 15, Brennan teaches a hydrophilic capture zone, and a hydrophobic non-wetting zone (column 5 lines 8-23, claim 3 b, d).
- 11. Regarding claim 17, Brennan teaches the operating zone having a chemical interaction with the sample (column 9 lines 16-23).
- 12. Regarding claim 19, Brennan teaches at least one operating zone for detection of a biological species present in the liquid sample (column 7 lines 60-62, column 9 lines 16-18).
- 13. Regarding claim 20, Brennan teaches the device wherein at least one operating zone is functionalized with a probe to interact with a target present in the sample liquid (column 7 lines 21-26, 45-48, 60-62).
- 14. Regarding claim 29, Brennan teaches the active surface consisting of glass (column 5 lines 8-19).
- 15. Regarding claims 30 and 45, Brennan does not explicitly teach an operating plate comprising several operating devices; however, this feature is being read as a duplication of parts which would have been obvious to one of ordinary skill in the art. The MPEP states that the "mere duplication of parts has no patentable significance unless a new and unexpected result is produced (MPEP 2144.04 VI B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the operating device of Brennan to include multiple operating devices as the duplication of parts requires only routine skill in the art.

- 16. Regarding claim 31, Brennan teaches the operating devices as an array (column 8 line 2, column 9 lines 16-18).
- 17. Regarding claims 32, Brennan teaches a dispenser wherein the dispenser delivers a drop of liquid per capture zone (column 8 lines 37-44).
- 18. Regarding claims 33, 35, and 38 Brennan teaches an operating box (figure 7) comprising, a container with means for introduction and withdrawal of a liquid (column 5 lines 56-67, figures 5 #'s 2 and 3), and an operating device (column 4 lines 38-43, figure 7 #6). The means for withdrawal of the liquid as taught by Brennan meets the limitations of the instant claim in that applicant does not indicate a specific mechanism for liquid withdrawal. Paragraph 0129 of the instant specification states that "withdrawal of the liquid can be carried out by any appropriate means known to those skilled in the art" therefore the withdrawal means taught by Brennan would be fully capable of performing as that of the instant claim.
- 19. Regarding claim 34, Brennan teaches a method of washing the array plate by flooding the surface with a liquid (column 8 lines 53-57. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the washing step as taught by Brennan to withdraw the sample liquid from the array surface in order to remove deposited samples prior to application of a different sample.
- 20. Regarding claim 44, Brennan teaches an operating box (figure 7) comprising, a container with means for introduction and withdrawal of a liquid (column 5 lines 56-67, figures 5 #'s 2 and 3), and an operating device (column 4 lines 38-43, figure 7 #6). The means for withdrawal of the liquid as taught by Brennan meets the limitations of the instant claim in that applicant does not indicate a specific mechanism for liquid withdrawal. Paragraph 0129 of the instant specification

states that "withdrawal of the liquid can be carried out by any appropriate means known to those skilled in the art" therefore the withdrawal means taught by Brennan would be fully capable of performing as that of the instant claim.

- 21. Claims 2, 3, 5, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Wohlstadter et al., (US 2001/0021534) as applied to claim 1 above, and further in view of Garyantes (US 6,565,813).
- 22. Regarding claim 2, Brennan in view of Wohlstadter et al., do not teach the capture zone having a particular shape.

Garyantes teaches a device comprising a plurality of wells having an annular circular shape (Abstract, column 8 lines 63-66, figure 6A). It would have been obvious to one of ordinary skill in the art to modify Brennan in view of Wohlstadter et al., in further view of Garyantes in order to provide an annular well that conforms to the shape of a liquid droplet. In addition, it would have been obvious to modify Brennan in view of Wohlstadter et al., in further view of Garyantes as changes in shape within a device require only routine skill in the art (see MPEP 2144.04 IV B).

23. Regarding claim 3, Brennan in view of Wohlstadter et al., do not teach a capture zone surrounding multiple working zones.

Garyantes teaches that it is advantageous to surround several hydrophilic zones with a hydrophobic zone in order to test multiple samples without contaminating each individual sample liquid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Wohlstadter et al., by

Art Unit: 1777

surrounding several hydrophilic zones with a hydrophobic zone in order to test multiple samples without contaminating each individual sample liquid.

Page 7

24. Regarding claim 5, Brennan in view of Wohlstadter et al., do not teach a capture zone being in a projection on the surface.

Garyantes teaches that it is advantageous to form the capture zone as a protrusion in order to allow formation of a virtual well for a hydrophilic layer (column 9 lines 37-45, 55, 56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Wohlstadter et al., with the protrusions of Garyantes in order to allow formation of a virtual well.

25. Regarding claim 16, Brennan in view of Wohlstadter et al., do not teach a capture zone and an operating zone in a hollow or as a projection relative to the surface.

Garyantes teaches that it is advantageous to form the capture zone or the operating zone as a hollow or a projection relative to the surface in order to allow formation of virtual wells for a hydrophilic layer (column 9 lines 37-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Wohlstadter et al., with the protrusions of Garyantes in order to allow formation of a virtual well.

- 26. Claims 6, 8, 9, 13, 14, 18, 21, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Wohlstadter et al., (US 2001/0021534) as applied to claim 1 above, and further in view of Heller (US 6,017,696).
- 27. Regarding claim 6, Brennan in view of Wohlstadter et al., do not teach a device wherein at least one capture zone is an electrode.

Heller teaches that it is advantageous to place electrodes in microlocation zones (capture zone) in order to control electrophoretic transport of molecules in a sample liquid (column 11 lines 6-10, 54-61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Wohlstadter et al., in further view of Heller by placing electrodes in microlocation zones (capture zone) in order to control electrophoretic transport of molecules in a sample liquid (column 11 lines 6-10, 54-61).

- 28. Regarding claim 8, applicant does not provide any structural limitations regarding the claimed electrode; therefore, the electrode taught by Brennan in view of Wohlstadter et al., in further view of Heller would be fully capable of capture by electrowetting as recited in the instant claim. Additionally, the instant claim is sufficiently broad so as to not overcome limitations taught by the prior art; therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan Wohlstader et al., in view of Heller in a manner wherein the electrode is configured for capture by electrowetting.
- 29. Regarding claim 9, Brennan in view of Wohlstadter et al., do not teach an electrode consisting of a noble metal.

Heller teaches that it is advantageous to construct electrodes from noble metals in order to complement other materials in the assay device (column 15 lines 36-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Wohlstadter et al., with the noble metal electrode of Heller in order to complement other materials in the assay device.

30. Regarding claim 13. Brennan in view of Wohlstadter et al., do not teach an electrode made of gold.

Heller teaches that it is advantageous to form electrodes from gold in order to complement other materials within the assay device (column 15 lines 36-40). The limitations of rendering the electrode wetting by physisorption of a thiol is regarded as intended use as there are various known methods of rendering an electrode wetting. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Wohlstadter et al., in further view of Heller to include a gold electrode in order to complement other materials in the assay device.

31. Regarding claim 14, Brennan in view of Wohlstadter et al., do not teach the wetting chemical as an alcohol.

Heller teaches a method of controlling molecular biological analysis and diagnostics wherein hydroxyl groups are utilized as the wetting agent for an aqueous solution (column 17 lines 4 and 5). Heller teaches that it is advantageous to utilize hydroxyl groups as a means of attaching permeation and attachment layers to the substrate (column 17 lines 4-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Wohlstadter et al., in further view of Heller to utilize hydroxyl groups as the wetting agent in order to facilitate binding of permeation and attachment layers as taught by Heller.

32. Regarding claim 18, Brennan in view of Wohlstadter et al., do not teach the operating zone as an electrochemical microcell.

Heller teaches a method for controlling molecular biological analysis and diagnostics comprising electrochemical microcells (figures 1 and 2). Heller teaches that it is advantageous to construct an electrochemical microcell in order to extract specific molecules from a sample

(column 12 lines 35-54). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Wohlstadter et al., in further view of Heller to utilize electrochemical microcells in order to extract specific molecules from a sample as taught by Heller.

33. Regarding claim 21, Brennan in view of Wohlstadter et al., do not teach an electrode of an electrochemical microcell.

Heller teaches a method for controlling molecular biological diagnostics and analysis comprising an electrochemical microcell wherein the electrode exhibits wetting properties (column 16 lines 18-22). Heller teaches that it is advantageous to construct an electrochemical microcell in order to extract specific molecules from a sample (column 12 lines 35-54). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Wohlstadter et al., in further view of Heller to utilize an electrochemical microcell comprising an electrode with wetting properties in order to extract compounds from a variety of aqueous solutions as taught by Heller.

34. Regarding claim 22, Brennan in view of Wohlstadter et al., do not teach an electrode with a probe to interact with a target sample liquid.

Heller teaches a method for controlling molecular biological diagnostics and analysis comprising an electrode with attached probes (column 16 lines 7-13, column 17 lines 4-13, 26-27). Heller teaches that it is advantageous to attach a probe to the electrode in order to extract specific target molecules from a sample (column 16 lines 7-13, column 17 lines 4-13, 26-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention

Page 11

Art Unit: 1777

was made to modify Brennan in view of Wohlstadter et al., in further view of Heller to attach a probe to an electrode in order to extract specific target molecules as taught by Heller.

35. Regarding claim 25, Brennan in view of Wohlstadter et al., do not teach an electrode having a biological probe attached.

Heller teaches a method for controlling molecular biological analysis and diagnostics wherein DNA, enzymes, and antibodies are utilized as probes (column 20 lines 13-25). Heller teaches that it is advantageous to utilize DNA, enzymes, and/or antibodies as a means of facilitating efficient binding and detection of a target of interest (column 20 lines 13-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Wohlstadter et al., in further view of Heller to utilize DNA, enzymes, or antibodies in order to improve specificity of a reaction by utilizing a probe the specifically binds a target molecule within the sample liquid.

- 36. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Wohlstadter et al., (US 2001/0021534) in view of Heller (US 6,017,696) as applied to claim 22 above, and further in view of Marx et al., (US 5,440,025).
- 37. Regarding claims 23 and 24, Brennan in view of Wohlstadter et al., in view of Heller do not teach a probe attached to an electrically conductive polymer.

Marx et al., teach a process for separating nucleic acid polymers wherein a substrate comprises a polypyrrole as an electrically conductive polymer (column 3 lines 32-39). Marx et al., teach that it is advantageous to utilize an electrically conductive polymer (polypyrrole) as a means of binding a nucleic acid without causing denaturation (column 3 lines 32-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to modify Brennan in view of Wohlstadter et al., in view of Heller in further view of Marx et al., to utilize an electrically conductive polymer in order to prevent denaturation of nucleic acids as taught by Marx et al.

- 38. Claim 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Wohlstadter et al., (US 2001/0021534) as applied to claim 33 above, and further in view of Grant et al., (US 5,624,815).
- 39. Regarding claim 36, Brennan in view of Wohlstadter et al., do not teach a suction pump for withdrawal of a sample liquid.

Grant et al., teach an apparatus for analysis of biological material comprising a suction pump for liquid removal (column 6 lines 63 and 64). Grant et al., teach that it is advantageous to utilize a suction pump in order to efficiently remove excess liquid (column 6 lines 63 and 64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Wohlstadter et al., in further view of Grant et al., to utilize a suction pump in order to efficiently remove excess liquid as taught by Grant et al.

- 40. Claims 39-41, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Wohlstadter et al., (US 2001/0021534) as applied to claims 1 and 30 above, and further in view of Rava et al., (US 5,545,531).
- 41. Regarding claims 39 and 46, Brennan in view of Wohlstadter et al., do not explicitly teach the device as a biological chip.

Rava et al., teach a device comprising multiple biological chips having probes exposed on the surface of a substrate for binding analytes in a liquid sample (abstract, column 4 lines 48-52). It would have been obvious to one of ordinary skill in the art at the time the invention was

Art Unit: 1777

made to modify the device of Brennan in view of Wohlstadter et al., in further view of Rava et al., in order to provide increased throughput, thereby allowing multiple biological samples to be analyzed on a single device.

- 42. Regarding claim 40, Brennan teaches a substrate for binding nucleic acids (Example 4).
- 43. Regarding claim 41, Brennan teaches the device as an operating box (column 8 lines 50-57, figure 7).

## Response to Arguments

- 44. Applicant's arguments with respect to claims 1-27 and 29-46 have been considered but are most in view of the new ground(s) of rejection.
- 45. At the outset, the Examiner acknowledges the amendments to claims 1 and 30 presented in the response filed on April 11, 2011. Applicant has amended claims 1 and 30 to recite a capture zone that is wetting with respect to a liquid of interest and an operating zone in which physical, chemical, or optical operations are performed, and argues that reference to Brennan does not teach all the claim limitations. The claims not stand rejected as being obvious over the combination of Brennan in view of Wholstadter et al., which the Examiner contends meets the limitations of claims 1 and 30. Applicant's view of reference to Brennan is that the device comprises an active surface with hydrophilic binding sites located on the active surface. The Examiner contends that Applicant's views are not the only reasonable interpretation of the teachings of Brennan and avers that it is wholly reasonable to interpret the device of Brennan as having structures analogous to the claimed capture and operating zones. Additionally, Applicants arguments appear to take the position that the liquid of interest is an aqueous solution; however, the Examiner contends that the liquid of interest can also be a hydrophobic

Art Unit: 1777

Page 14

solution (as claims 1 and 30 do not specify the makeup of the liquid) and would be wetting and non-wetting with the capture and operating zones based on the particular arrangement of the zones. In short, the Examiners position is that the function of being wetting and non-wetting is dependent on both the liquid of interest and the arrangement of the capture and operating zones. Claims 1 and 30 do not offer specifics regarding the liquid of interest and are thus open to interpretation with regards to being wetting and non-wetting in the respective zones. As detailed above, reference to Brennan is now modified with reference to Wholstadter et al., who teach a multi-array testing cartridge wherein the cartridge can have hydrophilic binding domains surrounded by hydrophobic regions and/or hydrophobic binding domains surrounded by hydrophilic regions. Wholstadter et al., teach that it is advantageous to form the hydrophilic/hydrophobic regions and binding domains relative to the sample that is applied in order to control the spread or wetting of a fluid or gel applied to the binding domains (paragraph 0159) thereby providing sufficient motivation to combine the references. Therefore, it is the Examiner's position that the limitations of claims 1 and 30 are taught by the combination of Brennan in view of Wholstadter et al., thus the rejection of claims 1 and 30 are maintained. With respect to the dependent claims, Applicant has argued that the claims are in condition for allowance based on their dependency from claims 1 and 30. As stated above, the Examiner does not believe that claims 1 and 30 are in condition for allowance, thus Applicant's arguments do not overcome the prior art rejections listed in the above Office Action.

Art Unit: 1777

## **Conclusion**

46. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1777

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DAG /Jill Warden/

Supervisory Patent Examiner, Art Unit 1773